K100781

510(k) Summary (K100781)

Submitter:

JUN 21 2010

Prismatik Dentalcraft, Inc.
4141 MacArthur Blvd.
Newport Beach, CA 92660

Contact Person(s):

Keith D. Allred, 949-440-2683 (p) / 949-440-2787 (f)
and consultants, Robin Carden & Wolfgang Freibauer

Date of Application: March 15, 2010

Identification of the Device: Obsidian™ Ceramic Blocks, product code "EIH," non-exempt Class II (CFR §872.6660 - Porcelain powder for clinical use)

Substantial Equivalence: The device is substantially equivalent to other legally marketed devices in the United States. Substantially equivalent devices include the following: (1) IPS e.max CAD/IPS e.max ZirCAD (Ivoclar, K051705); and (2), IPS Empress 2 (Ivoclar, K982616).

Description of the Device: The device is comprised of dental porcelain powder in the nature of a lithium silicate glass ceramic that is used in the form of ceramic blanks. The device has excellent casting and machining properties and can be used to obtain highly esthetic dental restorations with desirable characteristics including improved density and flexural strength compared to predicate devices.

Indications for Use: The device is used to fabricate ceramic dental prostheses in the nature of crowns and bridges for posterior and anterior applications using CAD/CAM or hot-press methods.

Safety and Efficacy: Studies comparing the subject device to predicate devices (e.max CAD– K051705 and IPS Empress 2 – K982616) demonstrate that the subject device is safe and effective for use fabricating restoratives in the nature of ceramic crowns, bridges, veneers, inlays and onlays using CAD/CAM and press-ceramic methods. Both the subject and predicate devices are lithium silicon glass ceramics and substantially identical in that they use the same basic components. The predicate devices contain lanthanum oxide whereas the subject device uses germanium dioxide, resulting in a lithium silicate glass ceramic with increased final density and higher values of flexural strength compared to lithium disilicate glasses.

Additionally, clinical data was provided for investigational purposes. CAD/CAM methods were used to mill twenty-eight custom made restorations using the subject device, comprising 27 crowns and 1 inlay for 16 patients. All of the restorations were placed from October 2, 2009 through May 4, 2010 demonstrating excellent esthetics (9 of the restorations have been in place from 6 to 9 months and 23 restorations have been in place for more than 3 months). All 28 restorations are performing as expected based on the physical properties of the subject device as determined in the nonclinical testing with no replacements required.

Conclusions drawn from the nonclinical and clinical data demonstrate that the subject device functions in a similar manner to other comparative devices and the intended use is the same. The fundamental scientific technology of the subject device has not changed relative to the predicate devices and the differences between the subject and predicate devices are minor and do not raise new safety concerns. The effectiveness and suitability to the intended purpose of the subject device are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification and are assured through wide, general use of similar other predicate devices that demonstrate the safe use of the subject device to construct dental restorations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 21 2010

Mr. Keith Allred
Prismatik Dentalcraft, Incorporated
4141 MacArthur Boulevard
Newport Beach, CA 92660

Re: K100781
Trade/Device Name: Obsidian™ Ceramic Blocks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH
Dated: May 19, 2010
Received: May 24, 2010

Dear Mr. Allred:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Schedule B

Indications for Use Statement

- 510(k) Number (if known): K100781
- Device Name: Obsidian™ Ceramic Blocks
- Indications for Use:

The device is used to fabricate ceramic dental prostheses in the nature of crowns and bridges for posterior and anterior applications using CAD/CAM or hot-press methods.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 SubpartD) (21 CFR 801 SubpartC)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100781